

Michigan Department of Community Health

Michigan BioTrust for Health

2013 Annual Report



www.michigan.gov/biotrust

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I. Introduction

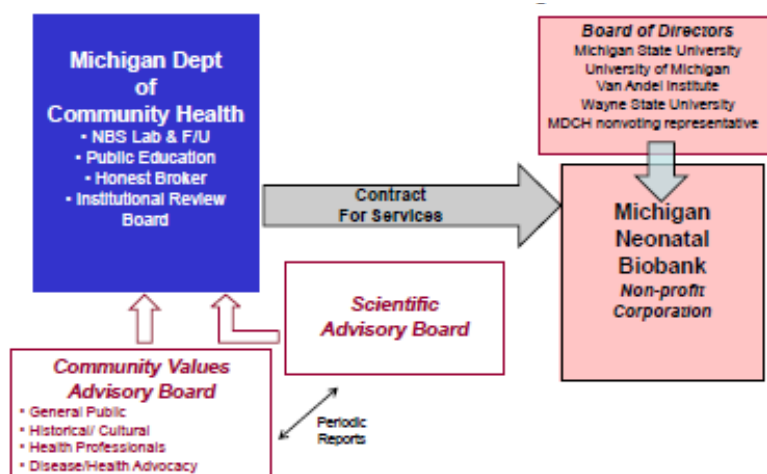
This Annual Report provides an overview of the Michigan BioTrust for Health (BioTrust) including the work accomplished by the Michigan Department of Community Health (MDCH), BioTrust Community Values Advisory Board (CVAB), BioTrust Scientific Advisory Board (SAB), and the Michigan Neonatal Biobank (MNB). Future BioTrust annual reports will be included as an appendix of the MDCH Newborn Screening Annual Report available each summer.

Background

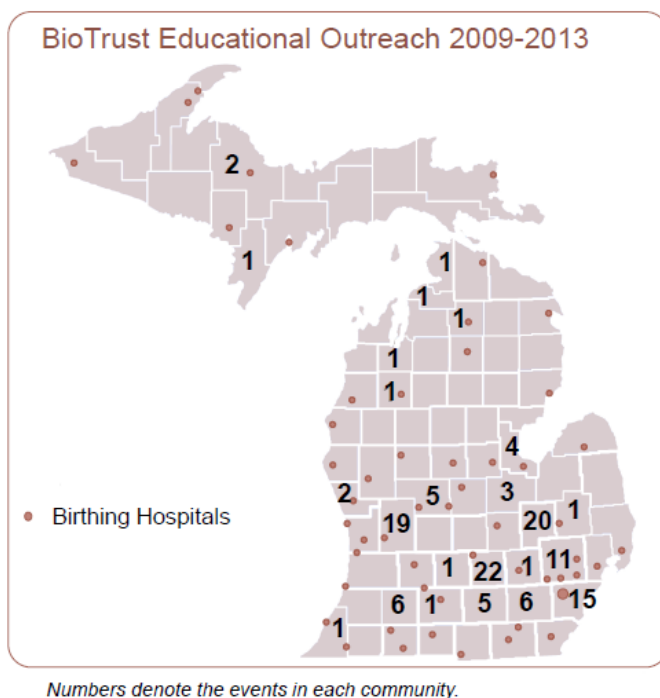
Following recommendations in 1999 from the Governor's Commission on Genetic Privacy and Progress, the Michigan Legislature amended the Public Health Code in 2000 to allow use of residual newborn screening blood spots in health research as long as human subjects' rights were protected. (MCL Section 333.5431)

Before and after the public health code was amended, MDCH used multiple methods to gauge interest in using residual newborn screening blood spots for research within the scientific community and to assess public acceptance. Researchers affirmed their interest and high levels of public support were ascertained. On June 1, 2009, MDCH announced that plans were proceeding to develop the BioTrust and concurrently convened the CVAB, an advisory board for guidance on policy development and community outreach pertaining to the BioTrust. MDCH also convened the BioTrust SAB in order to draw experts from various fields of research and health care to assess the scientific merit of research proposals requesting use of blood spots. MDCH partners in the BioTrust include Michigan State University, Van Andel Institute, University of Michigan and Wayne State University. The MNB, a 501(c)(3) non-profit organization, is the designated repository for the residual newborn screening blood spots.

Figure 1. Michigan BioTrust for Health Governance/Advisory Structure



Increasing community awareness of the BioTrust has been and will continue to be a priority. Approximately 130 exhibits or lectures have been given in order to raise awareness in communities across the state (Figure 2). Just under 30 Grand Rounds presentations have been given. Nurses at >80 hospitals statewide have been trained to administer the parental consent process for the BioTrust. In addition, 75 newsletter articles, webinars, email blasts and social media posts have been distributed. At least nine mass media segments on the BioTrust have appeared in written or televised press. MDCH staff has been invited to share BioTrust policies with attendees at five national conferences and four peer reviewed journal articles on the BioTrust have been published.



II. 2013 Updates

A. Educational Outreach and Evaluation

- BioTrust policies and program information were presented at the following national meetings:
 - Association Public Health Laboratories (APHL) Legal and Public Health Perspectives Surrounding Residual Dried Blood Spots in Newborn Screening (Atlanta, Georgia)
 - APHL Newborn Screening and Genetic Testing Symposium (Atlanta, Georgia)
- “From Newborn Screening to Population Health Research: Implementation of the Michigan BioTrust for Health” manuscript was published in *Public Health Reports* 2013, V128, N5: 377-384.
- Parental consent brochures and forms were revised and circulated state-wide following input from surveyed birthing hospital staff and parents. An audio recording of the new brochure was taped and posted on-line.
- On-line training modules for hospital staff were updated and instruction sheets for using revised BioTrust consent forms and educational material were distributed.
- Over 200 prenatal care provider offices were telephoned and/or emailed with BioTrust information and product order forms.
- 3 lectures/exhibits were provided to health care professionals.
 - Michigan State Medical Society (MSMS) Perinatal Health Conference, Troy
 - Oakwood Hospital Annapolis Grand Rounds, Wayne
 - Healthy Mothers Healthy Babies Conference, Bay City
- 9 activities were held to deliver BioTrust material to community members, legislators and media.
 - Beaumont Hospital Baby Fair, Royal Oak
 - Beaumont Hospital Baby Fair, Troy
 - Amish Midwife Training, Six Lakes
 - Newborn Screening 50th Celebration, Ann Arbor
 - Newborn Screening 50th Celebration, Detroit
 - Newborn Screening 50th Celebration, Grand Rapids
 - Newborn Screening 50th Celebration, Lansing
 - BioTrust and Newborn Screening information delivered by hand to all Michigan legislative offices, Lansing
 - Biopharmaceutical Vendor Day at the Capitol (meet and greet with legislators), Lansing
- On-line material was revised. The blood spot research report was updated, and a Community Blood Spot Research Report was developed for on-line viewing.
- MDCH Newborn Screening Follow-up Program received the Baby’s First Test 2013 Challenge Grant to improve the newborn screening rates amongst Michigan home births. As part of the grant, 34 of 51 midwives responded to a survey about newborn screening which included BioTrust questions and information.

- Of respondents, 72.7% expressed comfort in explaining the BioTrust. 79% provide the BioTrust consent booklet to most or every client and 54.5% discuss the BioTrust during prenatal visits.
- 10 of the midwife respondents requested additional BioTrust information.
- Two questions are included in Phase 7 of the Michigan Pregnancy Risk Assessment Monitoring System (PRAMS) to assess BioTrust education. PRAMS generates state-wide estimates of important perinatal health indicators among women delivering live infants. PRAMS staff collect data through a mailed survey with follow-up of non-respondents by telephone. Data from the questions will be available in 2014 or 2015.
 - Question 1: The Michigan BioTrust for Health is a program that uses leftover dried blood spots from newborn screening for health research. While pregnant, where did you hear or read anything about the BioTrust (*check all that apply*): childbirth education class; prenatal clinic or doctor's office; information packet from the hospital; health or baby fair; newspaper or magazine; other; I did not hear or read about the BioTrust while pregnant
 - Question 2: Around the time of your delivery, did the hospital staff or midwife give you a booklet about the Michigan BioTrust for Health, a program that uses leftover dried blood spots from newborn screening for health research (*check ONE answer*): No, I was not given the booklet; Yes, I was given the booklet, and it was easy to understand; Yes, I was given the booklet, and it was somewhat easy to understand; Yes, I was given the booklet but it was not easy to understand

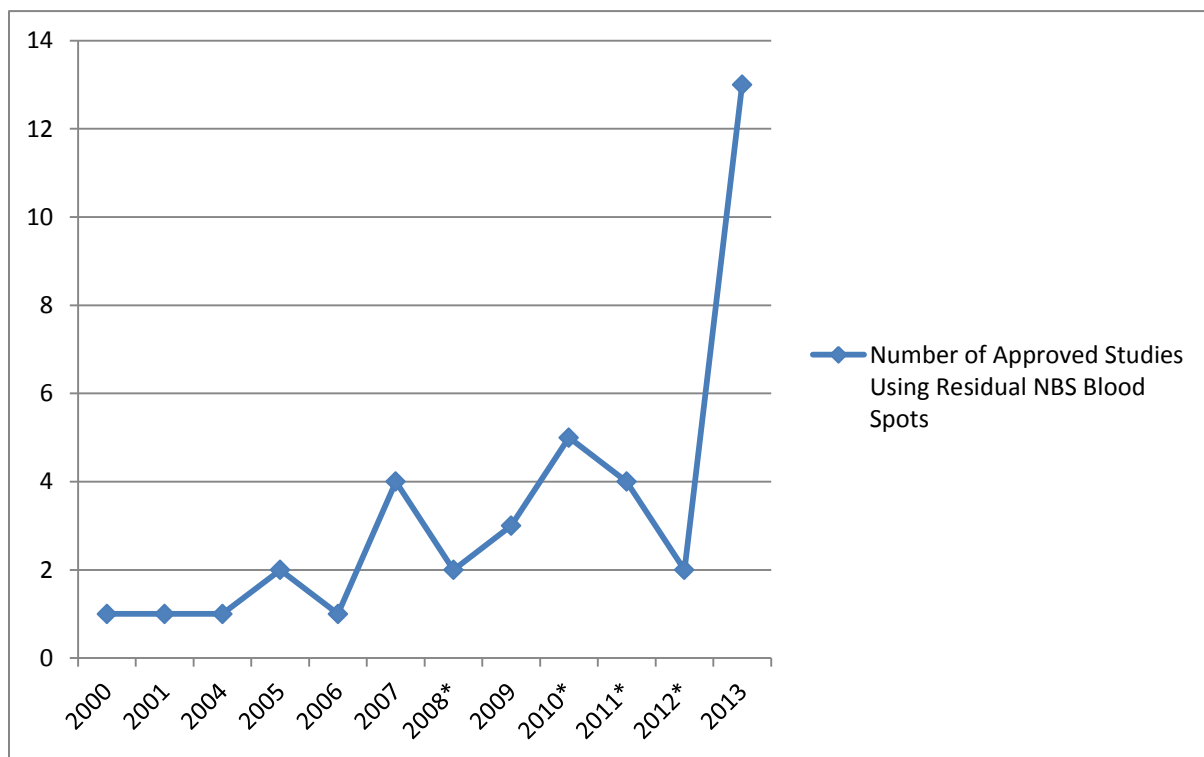
B. BioTrust Consent Process

- 20-30 birthing hospital coordinators were contacted on a quarterly basis, when performance metrics for the BioTrust consent process were not met, to ensure staff was actively taking part in the BioTrust parental consent process.
 - In 2013, newborn screening was performed on 112,063 infants. BioTrust parental consent forms, documenting either parent consent or refusal, were received from 79% of parents. Parental consent for research use of blood spots through the BioTrust was obtained from 60% (67,413/112,063). An additional 19% of parents (21,162/112,063) actively declined participation in the BioTrust. Another 21% of parental consent forms (23,488/112,063) were either not received or received incomplete and are considered passive declines.

C. Research Requests

- In 2013, 13 Proposals were reviewed by MDCH Institutional Review Board (IRB) and BioTrust SAB review panels and approved for use of residual newborn screening blood spots, representing a significant increase from previous years (Figure 3).

Figure 3. Approved Research Using Residual Newborn Screening Blood Spots, 2000-2013



**Two studies were originally approved (2008 and 2010) then amended for further work (2010 and 2012).*

III. BioTrust Community Values Advisory Board (CVAB)

The 2013-2014 CVAB roster (Table 1) was diversified in 2013 with the addition of 2 member-at-large seats following distribution of applications state-wide and on the BioTrust website. MDCH will seek representation for the 2015-2016 term from a student organization, tribal organization (Intertribal Council, former member), local public health organization and family advocacy organization. The CVAB met in February, June and September of 2013. All meeting dates are posted on the BioTrust website with an invitation for the general public.

The CVAB made it a priority to increase community awareness and BioTrust discourse within their own spheres of influence. Current and former CVAB members participated in 18 events in 6 cities as well as sharing MDCH social media posts (Table 2).

Table 1. 2013-2014 BioTrust Community Values Advisory Board Roster

| | Organization | Representative |
|-----------|---|---|
| 1 | American Cancer Society | Tom Rich |
| 2 | American Civil Liberties Union (ACLU) | Joyce Kornbluh |
| 3 | Arab Community Center for Economic and Social Services (ACCESS) | Pending |
| 4 | Cristo Rey | Mary Lou Mason, Designee John Roy Castillo |
| 5 | MichBio | Stephen Rapundalo |
| 6 | Michigan Association of Black Social Workers | Rita Walters |
| 7 | Michigan Association of Genetic Counselors (MAGC) | Tressa Orthmeyer, Designee Peggy Rush |
| 8 | Michigan Council for Maternal & Child Health | Sue Dendrinis |
| 9 | Michigan Developmental Disabilities Council | Tedra Jackson |
| 10 | Michigan Environmental Council | Tina Reynolds |
| 11 | Michigan Health and Hospital Association | Neil MacVicar |
| 12 | Michigan Minority Health Coalition | Rosalyn Beene-Harris |
| 13 | National Alliance on Mental Illness (NAMI) | Linda Burghardt |
| 14 | The Network for Public Health Law | Denise Chrysler |
| 15 | Member-at-Large | Ella Greene Moton |
| 16 | Member-at-Large | Karen Calhoun |

Table 2. 2013 Presentations by Current and Past BioTrust CVAB Members

| Presentations | CITY | 2013 |
|--|---------------------|----------------------|
| Bowl for Life | Flint | March and May |
| Senior Power Day | Genesee Township | May 22 |
| National Men's Health- Healthy Kappa's Health Communities | Saginaw | June 8 |
| Church of God in Christ Auxiliaries in Ministry Convention | Flint | June 13 |
| Worship Temple Women's Health Seminar | Flint | May 14 |
| Mt. Calvary Baptist Church Vacation Bible School | Flint | July 9 |
| Western Michigan's Jurisdiction Women's Convention | Benton Harbor | July 10 |
| Flushing Music in the Park | Flushing | July 24 |
| Our Savior Lutheran Urban Family & Community Health Fair | Flint | August 24 |
| UKF Annual Celebration of Life Gala | Grand Blanc | July 14 |
| Real Health for a Whole Community | Flint | September 25 |
| Community Diabetes/Influenza Outreach | Flint | October 16 |
| Flint/Genesee County National Influenza Week | Flint | December 8-14 |
| Community Based Organization Partners | Flint | Standing Agenda Item |

IV. BioTrust Scientific Advisory Board (SAB)

BioTrust SAB 2013-14 membership renewals were distributed with an invitation to 14 additional individuals. SAB renewal paperwork included a conflict of interest form (recommended following the 2012 joint BioTrust board meeting). SAB members represent Henry Ford Hospital, Michigan Bio-Industry, MDCH, Michigan State University, University of Michigan, Van Andel Institute and Wayne State University.

A task force of distinguished researchers and BioTrust SAB members met in 2013 to provide MDCH with guidance on various BioTrust policies and procedures. Action items from this meeting included revision to BioTrust policies to ensure blood spots associated with confirmed newborn screening diagnoses were not used in studies requesting blood spots from the general population. In addition, the recommendation was made that all blood spots currently in our archive (July 1984 through present day) remain in storage due to their potential use and value in future research unless a parent or individual over age 18 opts out.

In 2013, 15 proposals were submitted to MDCH for use of residual newborn screening blood spots and 13 were approved. A list of the approved studies is provided in Table 3. The remaining two are being prepared for the review and approval process in 2014. One proposal was also submitted for data only through the Newborn Screening Translation Research Network (NBSTRN) Virtual Repository of Dried Blood Spots. Research topics ranged from studying methods for improving newborn screening to assessing how environmental factors impact human development.

Table 3. 2013 Research Proposals Approved to Use Residual Newborn Screening Blood Spots

| Title | Institution |
|--|-------------------------------------|
| Lab-On-A-Chip for Multiplexed Newborn Screening of Metabolic Disorders-Assay Development | Advanced Liquid Logic |
| Gene-Environment Interplay and Young Children's Executive Functioning | Wayne State University |
| Improving IRT/DNA Newborn Screening for Cystic Fibrosis to Reduce False Positive Results by a New Molecular Strategy | Wisconsin Newborn Screening Program |
| Neural and Genetic Factors Contributing to Variants of Pediatric Anxiety Disorder | Wayne State University |
| Newborns Conceived Through IVF Technology and the Incidence of Genomic Anomalies: A Pilot Study in Epigenetics | Wayne State University |
| Identification of Genetic Causes of Tetralogy of Fallot Using Massively Parallel Sequencing | University of Michigan |
| Evaluation of the Effects of Prenatal Exposure to Non-essential Heavy Metals on Hearing | University of Michigan |
| Neurotoxin Exposure and Brain Development | University of Michigan |
| Bloodspot Environmental Epidemiology Project | Michigan State University |

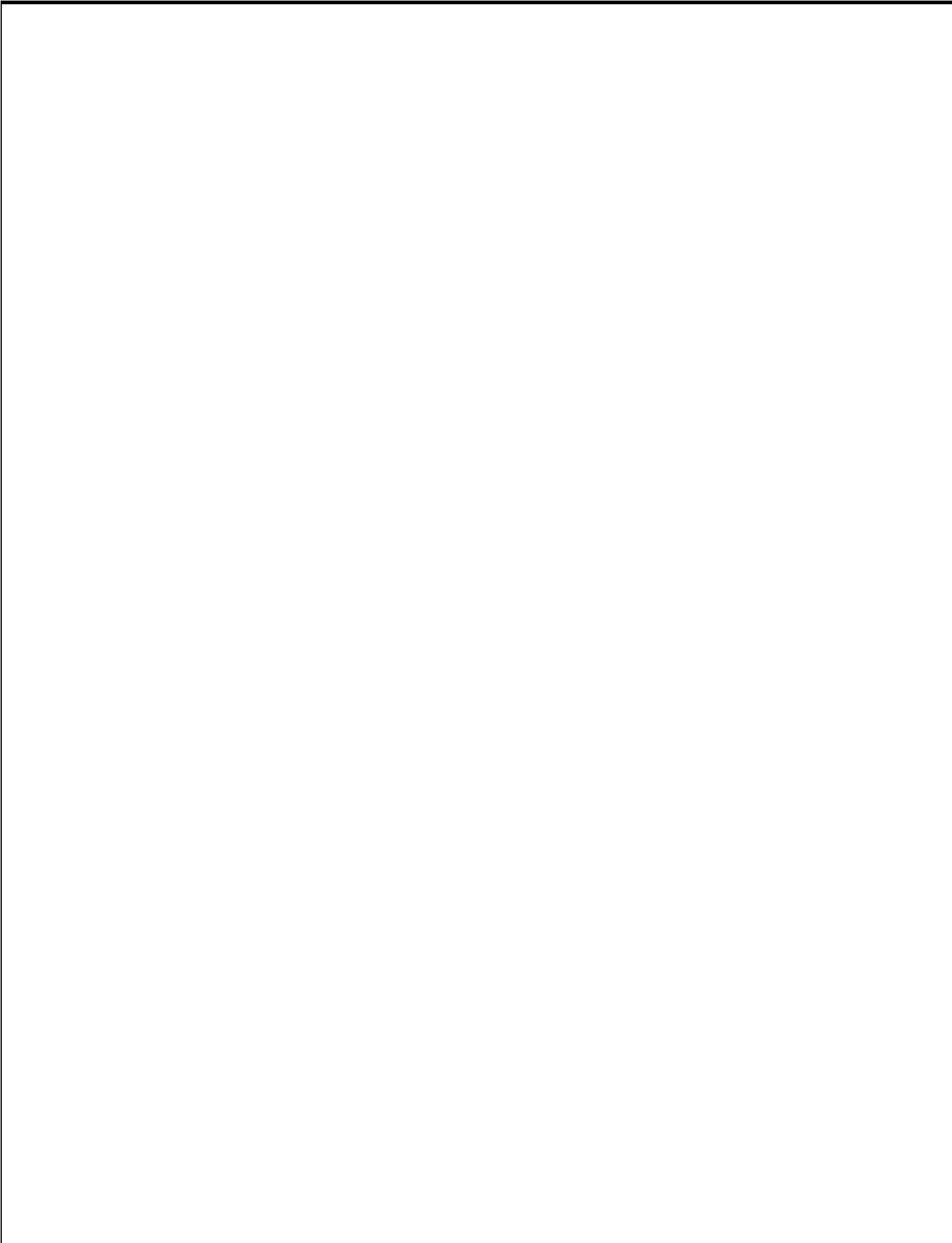
| | |
|--|---------------------------|
| Clinical Database of Children with Krabbe Disease: A World-Wide Registry | University of Buffalo |
| Ecologic Stressors, PTSD, and Drug Abuse in Detroit | University of Michigan |
| ARCH Sub-study: Effects of Maternal Physical Activity on Methylation Patterns in Offspring Blood Spots | Michigan State University |
| Next Generation Sequencing in the Newborn Period | University of Michigan |
| Metabolic Associations with Cystic Fibrosis and Congenital Hypothyroidism (<i>Data Only</i>) | University of Iowa |

V. Michigan Neonatal Biobank (MNB)

MNB staff continues to promote the use of Michigan's residual newborn screening blood spots to researchers across the state and nation. The CVAB had the opportunity to tour the MNB during their September meeting, and an article was recently published in MichBio's newsletter, BioMatters (Fall/Winter 2013 edition). Additional activities included:

- December 2013: Presentation, Detroit Medical Center Pediatricians, Detroit MI
- November 2013: Exhibit, American Public Health Association Annual Conference, Boston MA
- October 2013: Bloodspot Environmental Epidemiology Project Conference, Ann Arbor MI
- September 2013: Researcher Presentation (Wayne State University, University of Michigan and Michigan State University in attendance), Ann Arbor MI

During 2013 the MNB provided 3,940 punches from stored blood spots for 7 different studies. A walk-in freezer has been under construction at the biobank throughout 2013 and is expected to be operational in 2014/15. This freezer will hold blood spot cards frozen since January 2009 and all cards prospectively collected. As of January 1, 2014, there are 2,068,000 blood spot cards in storage at the MNB.





MDCH is an equal opportunity employer, services and program provider.